

Title 25. HEALTH SERVICES

Part 1. DEPARTMENT OF STATE HEALTH SERVICES

Chapter 37. Maternal and Infant Health Services

Subchapter P. Surveillance and Control of Birth Defects

Amendments §§37.301 – 37.306

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes amendments to §§37.301 - 37.306, concerning the surveillance and control of birth defects.

BACKGROUND AND PURPOSE

The amended sections correlate with current state law and allow for active data collection via electronic access.

Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 37.301 - 37.306 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

Amendments to §§37.301 - 37.306 provide for revisions to clarify active surveillance text. Amendment to §37.305 (4)(d) adds new language to provide guidance for remote electronic access active data collection. The new §37.303(10)(I) adds a clinical or medical laboratory to the type of Health Facility definitions.

FISCAL NOTE

Lucina Suarez, Ph.D., Director, Environmental Epidemiology & Disease Registries Section, has determined that for the first five-year period the sections are in effect, there will be no fiscal implications to state or local government as a result of enforcing or administering the sections as proposed, because there is no cost impact to state or local government.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Dr. Suarez has also determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections. There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Dr. Suarez has also determined that for each year of the first five years the sections are in effect, the public will benefit by added clarity to the definitions.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environment exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environment exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Mark Canfield, Ph.D. Department of State Health Services, PO Box 149347, MC 1964, 1100 West 49th Street, Austin, Texas 78756 (512) 458-7232, fax (512) 458-7330. Comments will be accepted for 30 days following publication of the proposal in the Texas Register.

STATUTORY AUTHORITY

The proposed amendments are authorized by Health and Safety Code, §87.021, which requires the department to adopt rules on the operation of the birth defects program; §87.022 which requires the department to adopt rules on how information will be collected and made available; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules reasonably necessary for the department to administer its regulatory and administrative functions.

The proposed amendments affect Health and Safety Code, Chapters 87 and 1001; and Government Code, Chapter 531. Review of the rules implements Government Code, §2001.039.